UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

NATIONAL ASSOCIATION OF CHAIN DRUG STORES; NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, and the WASHINGTON STATE PHARMACY ASSOCIATION, Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of United States Department of Health and Human Services, and ELIZABETH RICHTER, in her official capacity as Acting Administrator for the Centers for Medicare & Medicaid Services, Defendants.	Case No. 2:21-cv-00576 COMPLAINT

Plaintiffs, the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the Washington State Pharmacy Association, allege the following for their Complaint against Xavier Becerra, Secretary of United States Department of Health and Human Services, and Elizabeth Richter, Acting Administrator for the Centers for Medicare & Medicaid Services, both named in their official capacities:

I. INTRODUCTION

1. Washington's Medicaid agency (the "State") does not adequately reimburse pharmacies for the health care services rendered to Medicaid beneficiaries. The State

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reimburses its pharmacies serving Medicaid beneficiaries at the lowest rate in the country. Its rate is *less than one-half* the rates paid by all neighboring states. These low rates have been in force and have actually decreased over the past sixteen years.

2. In 2016, Centers for Medicare & Medicaid Services ("CMS") promulgated a new rule that required all States to reassess their reimbursement rates and take into account the actual costs that pharmacies incur in serving Medicaid beneficiaries. State had to provide certain adequate and reliable data to support any change of its rate to ensure that these costs were adequately covered.

3. In response to that rule, the State insisted that its low rates remained appropriate even though it never conducted a cost-of-dispensing study or otherwise considered adequate and reliable data to support that conclusion—notwithstanding the fact that such studies were performed or data was provided by nearly every other state. The State then submitted its unchanged rate to CMS for federal approval.

4. Over the past several years—from 2017 through the end of 2020—CMS has taken the consistent position that the State's reimbursement rate violated federal law.

5. In September of 2018, CMS formally disapproved the State's formal rate proposal—known as a "State Plan Amendment"—because the State calculated its reimbursement rates unlawfully to keep them at an artificially low level. Consistent with CMS's longstanding position, and following an administrative evidentiary hearing, on July 31, 2020, a CMS Administrative Law Judge ("ALJ") recommended that the Secretary of United States Department of Health and Human Services ("HHS") uphold the denial of the State Plan Amendment 17-0002 (the "SPA").

6. Despite an administrative record containing none of the necessary cost data to substantiate the below-cost rates, the Secretary (acting through the former CMS Administrator) instead did an about-face. The Secretary ultimately rejected the agency's prior statements, guidance, specific regulations, and its own ALJ's recommended decision.

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The Secretary's wholesale rejection of CMS's prior positions came in the form of a one-page, summary decision signed the day *before* Inauguration Day and which constituted one of the CMS Administrator's last official acts in office before resigning.

7. The Secretary's conduct[1] was arbitrary and capricious because it completely ignored the years of prior and consistent agency communications that the State's reimbursement methodology violated federal law because it did not fulfill the required standards. Moreover, the final administrative decision also wholly ignored the well-reasoned recommended decision by the CMS ALJ who recommended that the State Plan Amendment be denied. The decision also violates CMS's own statutes and regulations governing the type of data needed to support an appropriate pharmacy reimbursement rate methodology.

8. The Plaintiffs here, all associations whose members include Washington State pharmacies that serve Medicaid beneficiaries, file this complaint under the Administrative Procedure Act to seek judicial review of the Secretary's final administrative decision. Plaintiffs request that the Court reverse the Secretary's final administrative decision and remand the matter back to the agency directing the Secretary to adopt the ALJ's decision to affirm denial of the SPA. In the alternative, Plaintiffs request the Court reverse the final administrative decision, remand the matter back to the agency directing the Secretary to again review the administrative record and the applicable law for reconsideration of a final determination on the SPA consistent with the Court's Order.

II. PARTIES

9. Plaintiff, National Association of Chain Drug Stores ("NACDS"), represents traditional drug stores, supermarkets, and mass merchants with pharmacies, and supplier

[1] Plaintiffs recognize that neither the current named Secretary nor the current CMS Administrator presently in office were involved in the underlying final administrative action. However, the current officials are named in their official capacity only consistent with the requirements of the Administrative Procedure Act.

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partners. NACDS is headquartered in Alexandria, Virginia. NACDS includes over 15 member-companies in Washington State operating over 960 pharmacies—many of which participate in Washington's Medicaid program.

10. National Community Pharmacists Association ("NCPA") is a non-profit based in Alexandria, Virginia. NCPA represents the interests of the owners, managers, employees, and patients of 21,000 independent community pharmacies across the United States. These pharmacies and their pharmacists are rooted in the communities that they serve and pride themselves on connecting and consulting with patients. Together, these independent pharmacies represent a $76 billion health care marketplace and employ more than 250,000 individuals on a full- or part-time basis. NCPA advocates on behalf of community pharmacists on public policy issues that directly affect their patients—including those in Washington State.

11. Plaintiff, Washington State Pharmacy Association ("WSPA"), represents pharmacists, technicians, and interns practicing within community pharmacies, as well as clinics, nursing homes, and hospitals. WSPA is headquartered in Renton, Washington, and many of its members participate in Washington's Medicaid program and provide care to Medicaid patients throughout Washington's urban, rural, and underserved communities.

12. Defendant Xavier Becerra is the Secretary of the United States Department of Health and Human Services, which is headquartered in Washington, D.C.

13. Defendant Elizabeth Richter is the Acting Administrator for the Centers for Medicare & Medicaid Services, which is headquartered in Woodlawn, Maryland.

III. JURISDICTION AND VENUE

14. This Court has federal question jurisdiction under 28 U.S.C. § 1331.

15. Plaintiffs' claims are pursuant to the Administrative Procedure Act ("APA") as codified at 5 U.S.C. § 701 et seq. Defendants have failed to comply with, among other things, Section 1902(a)(30)(A) of the Social Security Act ("the Act" or "SSA") (42 U.S.C. §

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1396a(a)(30)(A)), and with Federal regulations at 42 C.F.R. §§ 447.502, 447.512, 447.514, and 447.518.

16. Plaintiffs are three non-profit associations whose members include many Washington pharmacies participating in the Medicaid program. Collectively, Plaintiffs represent those pharmacies most affected by CMS's final administrative decision approving the SPA. Plaintiffs bring this action to seek judicial review of the Defendants' final administrative decision and request that the decision be reversed as unlawful and arbitrary and capricious and sent back to the agency for further action per the Court's Order.

17. Venue in this judicial district is appropriate under 28 U.S.C. § 1391. Plaintiffs each "reside" in this judicial district for the purposes of 28 U.S.C. § 1391 as each association has substantial membership operations in Washington and no real property interests are at stake in this action. The Washington State Pharmacy Association's offices are located within this judicial district. Moreover, a substantial part of the events or omissions giving rise to this claim occurred within this judicial district. The State of Washington's Medicaid State Plan Amendment was submitted by the State Medicaid agency within this district and the applicable reimbursement rates in question are paid to pharmacies within this judicial district. Lastly, the Defendants' agencies, the U.S. Department of Health of Human Services and Centers for Medicare and Medicaid Services both maintain offices and operations within this judicial district.

IV. FACTUAL ALLEGATIONS

A. Plaintiffs' standing and right to seek judicial review

18. Plaintiffs have multiple members who are suffering actual and cognizable injury as a result of the Secretary's final administrative decision approving the State's SPA. These pharmacies have and will continue to be reimbursed at a rate that is unlawfully too low because it fails to consider or account for the actual costs associated with filling the prescriptions for Medicaid beneficiaries as required by law.

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19. Further, Plaintiffs' individual members would otherwise have standing to sue in their own right, the interests Plaintiffs seek to protect are germane to each of the associations' purpose, and neither the APA claim and single declaratory claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

B. Federal Medicaid Law

20. Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.*, establishing the Medicaid program, authorizes federal financial support to states for medical assistance to low-income persons who are aged, blind, disabled, or members of families with dependent children. The Medicaid program is jointly financed by the federal and state governments, and administered by the states. The states, in accordance with federal law, decide eligible beneficiary groups, types and ranges of services, payment levels for services, and administrative and operative procedures. Payment for services is made directly by states to the individuals or entities that furnish the services. *See* 42 C.F.R. § 430.0.

21. In order to receive matching federal financial participation, states must agree to comply with the applicable federal Medicaid law and regulations. *See* 42 U.S.C. § 1396 *et seq*.

22. Federal law requires each state's Medicaid program to be administered by a single state agency, which is charged with the responsibility of establishing and implementing a State Medicaid Plan (the "State Plan") that complies with the provisions of applicable federal Medicaid law. *See* 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10. Each State Plan must provide for the provision of certain services, including payment for covered outpatient drugs (which are mandatory services that each state that participates in the Medicaid program is required to provide). *See* 42 U.S.C. § 1396r-8.

23. Pursuant to 42 U.S.C. § 1396a(a)(30)(A) ("Section 30"), each State Plan must: "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan

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at least to the extent that such care and services are available to the general population in the geographic area[.]"

24. Each state must submit their State Plan to CMS for approval. *See* 42 U.S.C. § 1396a(a); 42 C.F.R. § 430.10. Any amendment to a State Plan must also be submitted to CMS for approval. 42 C.F.R. § 430.12(c).

25. The Secretary of HHS, of which CMS is a part, must evaluate each state's compliance with the Medicaid statute. 42 U.S.C. §§ 1316(a)–(b), 1396a(b).

C. CMS changes how pharmacies are to be reimbursed

26. In February 2016, CMS promulgated a new regulation that fundamentally changed the methodology of how state Medicaid agencies reimburse pharmacies participating in the Medicaid program. *See* 81 Fed. Reg. 5170 (2016) ("CMS Rule").

27. The CMS Rule requires states to adopt reimbursement rates that cover the actual costs incurred by pharmacies participating in Medicaid, by reflecting those costs in two distinct components: (1) the ingredient costs and (2) the professional dispensing fees (dispensing fees). 42 C.F.R. §§ 447.502, 447.512(b), 447.514(b)(1), 447.518(a)(2).

28. Further, when proposing changes to *either* the ingredient costs and dispensing fees reimbursement rates, states "must consider *both* the ingredient cost reimbursement *and* the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of Section 1902(a)(30)(A) of the [Social Security] Act." 42 C.F.R. § 447.518(d) (emphasis added).

29. The purpose of the CMS Rule is to provide more fair and accurate reimbursements and to do so by moving away from basing ingredient costs on estimated costs to basing them on "Actual Acquisition Cost," also known as "ACC." 42 C.F.R. § 447.502, 447.512(b), 447.518(a) (2).

30. The CMS Rule defines ACC as the "actual prices paid to acquire drug products marketed or sold by specific manufacturers." 42 C.F.R. § 447.502.

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31. Similarly, the CMS Rule defines "professional dispensing fees" as requiring that reimbursements adequately cover a list of specified "pharmacy costs" associated with operating pharmacies. *See id*. (definition of "professional dispensing fees" at subparagraph (2)).

32. In particular, the CMS Rule defines dispensing fees as those "incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed" and "[i]ncludes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary." *Id*. Each state must submit proof that dispensing fees reimbursement rates cover those costs. *Id*. at § 447.518(b).

33. Additionally, states must also "*provide adequate data* such as a State or national survey of retail pharmacy providers or other *reliable data* other than a survey to support any proposed changes to … the components of the reimbursement methodology." 42 C.F.R. § 447.518(d) (emphasis added).

34. Finally, states "must submit to CMS the proposed change in reimbursement and the supporting data through a State plan amendment through the formal review process." *Id*.

D. <u>Washington submits its State Plan Amendment without meeting the requirements of the CMS Rule or federal law.</u>

35. In response to the new CMS Rule, in May 2016, the State engaged in a rulemaking that did not properly consider both the ingredient costs and the professional dispensing fees for Washington pharmacies serving Medicaid beneficiaries.

36. The State's rulemaking did adjust the ingredient costs methodology. But modifying the ingredient costs was just one part of the equation. The CMS Rule also requires that states "evaluate each component when they propose changes[,]" which includes the dispensing fee. 42 C.F.R. §§ 447.502, 447.512(b), 447.514(b)(1), 447.518(a)(2).

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37. The State failed to "evaluate [its] proposed changes in accordance with [the] final [CMS] rule, and . . . [to] consider the impacts of *both* the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes…" as legally required. 42 C.F.R. § 447.518(d) (emphasis added).

38. On March 2, 2017, the State announced that the dispensing fees for all Washington pharmacies across the state would remain flat at their 2009 levels, which ranged from $4.24 to $5.25 per prescription depending on the volume at a particular pharmacy.

39. The State's only justification for leaving the rates from 2009 unchanged was that they were still two to four times higher than what *private* insurers pay.

40. After adopting its rule, the State prepared a "Concise Explanatory Statement" summarizing the rule, as well as its response to any comments received. But nothing in its statement discussed the cost-based data or assessments used in calculating the adequacy or amount of professional dispensing fees.

41. The State's rule became effective on April 1, 2017. Thereafter, the State submitted its SPA to CMS for consideration.

E. ECMS questions the validity of the State's decision to leave its dispensing fees unchanged

42. Beginning in June 2017, CMS, the federal agency that must ultimately approve the State's proposed reimbursement rates, questioned the validity of the State's decision to leave its dispensing fees unchanged, asking the State to submit either a recent Washington state survey of pharmacy providers' actual cost of dispensing or data from neighboring states' recent cost of dispensing studies to support the proposed rates.

43. CMS's concern was based, in part, on Washington's status as an outlier on reimbursement rates. As compared to its neighboring states, Washington has the lowest reimbursement rate by far:

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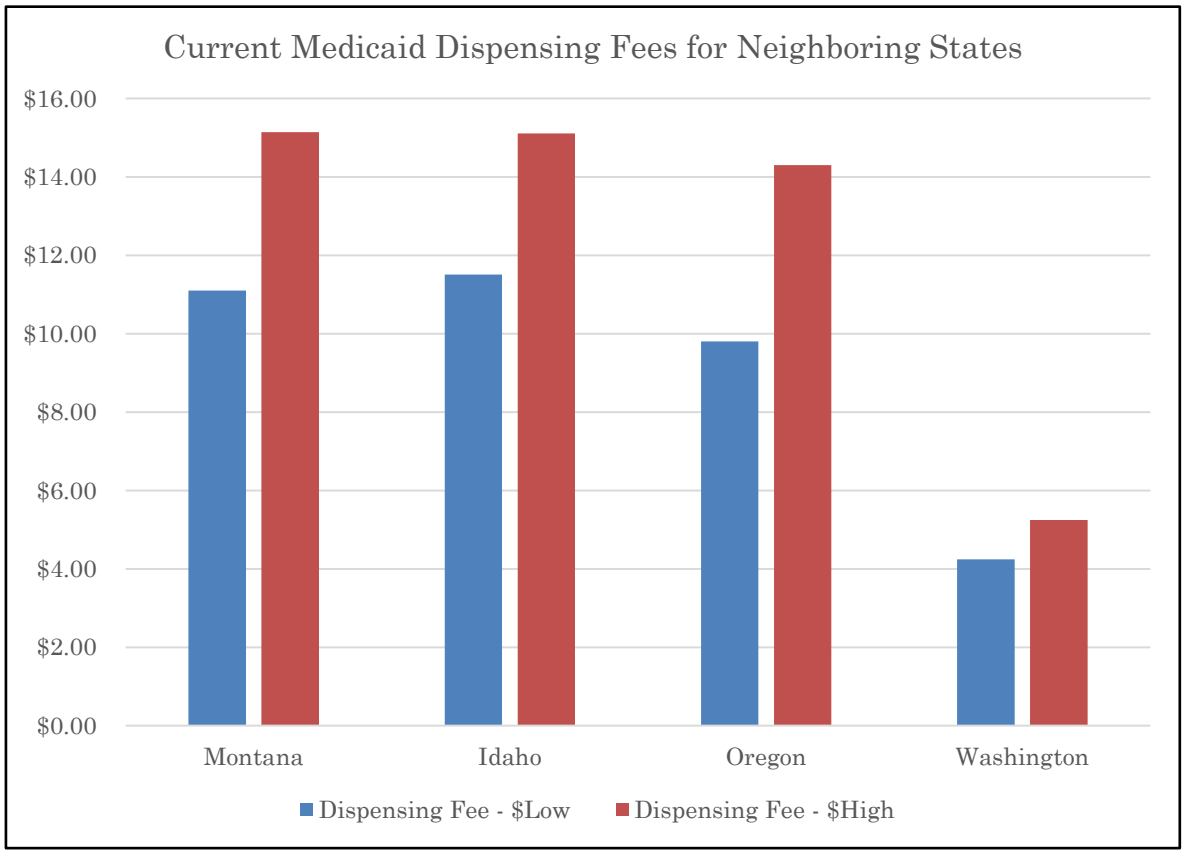

44. Beyond its regional neighbors, Washington's dispensing fee is also dead last in the nation—and by a significant amount.

45. The table below demonstrates that Washington's dispensing fee is significantly lower than all other approved state dispensing fees.[2]

[2] Some states, like Washington, have a "low" and "high" dispensing fee that depends on the volume of prescriptions filled. In general, pharmacies dispensing lower volumes of prescriptions are typically reimbursed at the higher fee, while pharmacies dispensing higher volumes of prescriptions are reimbursed at the lower fee.

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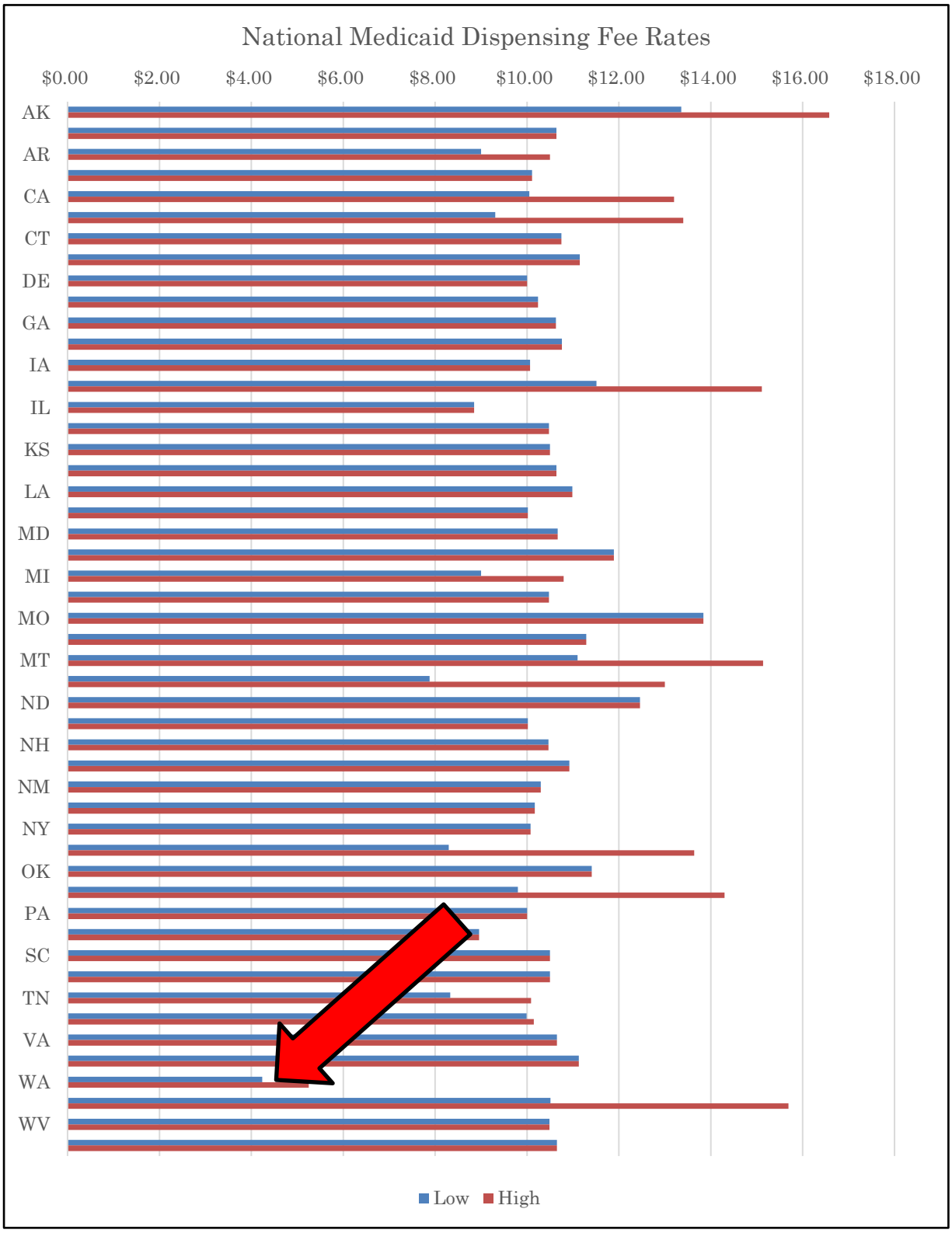

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46. When pressed by CMS, the State conceded that it has no such cost-based survey or data from its own state or from neighboring states that would support its proposed rates.

47. CMS asked for additional support that centered upon the actual cost to fill prescriptions beyond the previously submitted fee based studies to justify the State's proposed dispensing fee reimbursement rate.

48. The State declined to provide the requested material and merely reiterated that it was relying upon fee based studies of what *private* insurers pay, arguing that the "aggregate ingredient cost and dispensing fee rates are sufficient to ensure that . . . providers are adequately reimbursed in accordance with the requirements of § 1902(a)(30)(A) of the Social Security Act."

49. On September 10, 2018, CMS disapproved Washington SPA 17-0002. CMS's Letter from Tim Hill, Acting Director, is attached hereto, and incorporated herein, as **Exhibit A**.

50. In its disapproval letter, CMS noted that the regulation at 42 C.F.R. § 447.518(d) dictates that when a state proposes changes to either the ingredient or dispensing reimbursement to pharmacies, it must consider both costs to ensure that "total reimbursement to the pharmacy provider is in accordance with section § 1902(a)(30)(A) of the Act." *See id.*

51. CMS also quoted the final CMS Rule, which requires that "states must provide information supporting any proposed change to either the ingredient cost or dispensing fee reimbursement which demonstrates that the change reflects actual costs and does not negatively impact access." *Id.* The letter confirmed that the denial decision was made "after consultation with the Secretary." *Id.*

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F. The State files a request for reconsideration and the SPA denial is upheld following an administrative hearing

52. On November 5, 2018, the State filed a request for reconsideration with CMS.

53. Through a letter dated December 3, 2018 (published in the Federal Register at 83 Fed. Reg. 62869 (Dec. 6, 2018)), the CMS Administrator scheduled a subject hearing in response to the State's request for reconsideration.

54. A hearing was held on June 18, 2019, and on July 31, 2019, a CMS ALJ issued a 16-page, well-reasoned decision that recommended that CMS's SPA denial be upheld. A true and correct copy of the ALJ's decision is attached hereto, and incorporated herein, as **Exhibit B**.

55. The ALJ decision, in essence, found that the State had failed to support its decision to keep dispensing fee rates unchanged and below cost because it failed to conduct a cost of dispensing survey or otherwise provide any relevant, reliable, or adequate data reflecting the actual cost of dispensing for pharmacies serving Medicaid beneficiaries. *See id*.

56. The ALJ further recognized that the administrative record contained evidence that "Washington's rates were less than one-half the rates being paid in neighboring states" and that the State "did not provide adequate data to support that its 8-year old rates supported the current costs to dispense prescriptions." *Id*. at 10.

57. Under the law, the ALJ recommendation then went to the CMS Administrator to render a final administrative decision on the SPA's approval or denial.

G. The Principal Deputy Administrator of CMS enters a one-page ruling "approving" the State's SPA.

58. Despite the ALJ's well-reasoned decision and contrary to years of CMS's prior communications that the SPA did not meet federal law, on January 19, 2021, the "Principal Deputy Administrator" of CMS entered a one-page final administrative decision that "approved" the State's SPA (the "CMS Ruling"). A true and correct copy of the CMS final administrative decision is attached hereto, and incorporated herein, as **Exhibit C**.

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59. The final administrative decision contained no legal analysis other than stating that the text of the CMS Rule did not foreclose the State from using its "market-based" approach in setting rates. *See id*.

60. The final administrative decision was issued on January 19, 2020—less than 24 hours before Inauguration Day—and, on information and belief, constituted one of the last official acts of the outgoing CMS Administrator before resigning.

V. COUNT I

ADMINISTRATIVE PROCEDURE ACT, 5 U.S.C. §§ 701-706

61. Plaintiffs hereby incorporate by reference the prior paragraphs of this Complaint, as though fully set forth herein.

62. Under the federal APA, 5 U.S.C. §§ 701-706, courts "shall" overturn agency action that is arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with the law. 5 U.S.C. § 706. Courts shall also overturn agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *Id*.

63. Plaintiffs have suffered a legal wrong because of the Secretary's wrongful approval of the SPA and have been adversely affected. Plaintiffs are entitled to judicial review pursuant to 5 U.S.C. § 702.

64. The Secretary's final administrative decision approving SPA 17-0002 is the act of an administrative agency and subject to review under the APA.

65. The Secretary's approval of the SPA insofar as it pertains to the adequacy or amount of cost-based professional dispensing fee reimbursement rates is invalid under the APA because it is arbitrary, capricious, and an abuse of discretion, and otherwise inconsistent with governing law, because the data before the Secretary did not address the CMS Rule's own required elements for a cost-based professional dispensing fee.

66. The Secretary blindly approved the SPA without considering the appropriate underlying data (or lack thereof) in the administrative record that would have been necessary

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to confirm that Washington's SPA complied with CMS's own statutes and regulations for a cost-based professional dispensing fee. The State never submitted either a recent Washington state survey of pharmacy providers' *actual cost* of dispensing to Medicaid patients or data from neighboring states' recent cost of dispensing studies to support the proposed rates, as requested by CMS.

67. There also was no analysis of whether the rates are consistent with efficiency, economy and quality of care, and there was no analysis of whether the rates are reasonably related to the costs incurred by efficient economical providers. Moreover, the Secretary did not consider the level of service to Washington Medicaid patients relative to the general public (*i.e.*, non-Medicaid patients), as required by federal law. The Secretary failed to consider those important aspects of Section 30(A).

68. Further, the Secretary's decision was so conclusory, and lacking in any appropriate legal analysis, that it completely ignored the underlying CMS Rule and violated the agency's own law.

69. Finally, the Secretary's decision was directly contrary to years of CMS's prior communications, positions, and policies that the SPA did not meet federal law, as well as the ALJ's well-reasoned decision that recommended the SPA be denied.

VI. COUNT II

DECLARATORY RELIEF

70. Plaintiffs hereby incorporate by reference the prior paragraphs of this Complaint, as though fully set forth herein.

71. An actual and justiciable controversy exists between Plaintiffs and the Secretary regarding whether SPA 17-0002, which lowered ingredient costs while keeping dispensing fees unchanged without considering the costs of dispensing, complied with the requirements of the Federal Medicaid Act and the CMS Rule. Plaintiffs contend that it does

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not comply with the law and, accordingly, that the Secretary's approval of the SPA was arbitrary, capricious, an abuse of discretion, and not in accordance with applicable law.

72. Plaintiffs request that this Court declare the SPA as it relates to dispensing fees invalid, unlawful, and otherwise contrary to federal law pursuant to 28 U.S.C. § 2201.

73. No administrative appeal process or other administrative remedy is available to Plaintiffs to challenge the dispensing fees reimbursement rates in the SPA or the Secretary's approval of the SPA.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

1. For an Order declaring that it was arbitrary, capricious, an abuse of discretion, and not in accordance with applicable law for the Secretary to approve the SPA, which left the dispensing fee reimbursement rates unchanged since 2009;

2. For an Order setting aside the Secretary's final administrative decision approving SPA 17-0002 and remanding the matter to CMS and directing the agency to adopt the ALJ's recommendation to uphold the denial of the SPA; or, in the alternative, to review the administrative record and applicable law for reconsideration of a final determination on the SPA consistent with federal law and the Court's Order;

3. For a Declaration that the Secretary's approval of SPA 17-0002 was contrary to law and violated the APA and the Medicaid Act;

4. For an award of the costs of suit to Plaintiffs, including reasonable attorney fees, as permitted under 42 U.S.C. § 1988 or otherwise, and

5. Such other and further relief the Court deems just and proper.

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Dated this 29th day of April, 2021.

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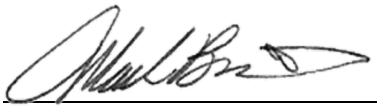
By: 

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